



MARYLAND Department of Health

Guidelines for Food Establishment Construction Sanitary Practices:

Food Manufacturing/Processing/Warehousing/Distribution/Wholesale

The following document is not intended to be an all-inclusive list of rules for manufacturer/processors, distributors and warehouses, but is intended to serve as a guideline and reference material.

The Code of Maryland Regulations (COMAR) 10.15.04 sets forth the standard for food establishments manufacturing and processing food in Maryland. It addresses prohibited acts, adulteration and mislabeling of foods among other things. The state of Maryland promulgates its own regulations, and also invokes all of the Federal Acts, Code of Federal Regulations (CFRs), relating to food. Therefore, there will be references to both the COMAR for food and the CFRs jointly throughout this document.

As foods and their processing methods are unique and customized, the Good Manufacturing Practices CFR's governing processed/manufactured foods can be broad and non-specific; however, there are specific food standards for some categories of food.

Updated Current Good Manufacturing Practices (cGMPs)

The FDA Current Good Manufacturing Practice (cGMP) requirements found in 21 CFR 110 has been revised as part of the FSMA new Preventive Controls rule and are now replaced by 21 CFR 117, subpart B. Both parts 110 and 117 will be cross referenced throughout this document. The revised cGMPs will continue to support Hazard Analysis Critical Control Point (HACCP) for juice and seafood as well as support the new Food Safety Plan required for other food processors. The new updates include:

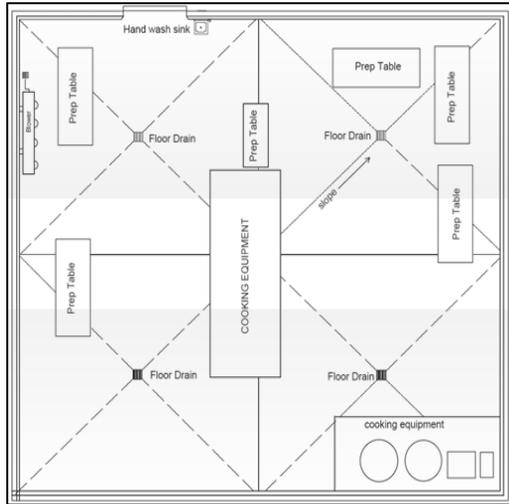
- Clarifications on protections against cross-contact of food by allergens
- Deletion of certain nonbinding provisions (language containing recommendations)
- Required Recall Plan, Sanitation Standard Operating Procedures (SSOPs)
- Standard Operating Procedures for manufacturing a specific food product (SOPs)

The present document will address the general construction, equipment and sanitation requirements as per the current and updated good manufacturing practices found in 21 CFR Part 110 and Part 117, subpart B and in COMAR for Food.

FLOORS

Key Points: smooth, impervious, trapped drains, no pooled water, sloped to drain as applicable

The floors of all rooms in which food products are handled, processed, packaged or stored; or in which food containers, utensils and/or equipment are washed shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped so that there are no pools of standing water after flushing, and the joints between the floor and the walls are both coved and impervious to water, and shall be provided with trapped drains in good repair at the rate minimum rate of one floor drain for each 400 square feet of area. Floors, when receiving water as a result from processing or cleaning are sloped to one or more floor drains at a pitch of 1/8 to 1/4 inch per foot.



Regulations on this area can be found in:
Code of Maryland Regulations (COMAR) 10.15.04.09
 21 CFR 110.20(b)(4), 110.37(b)(4), 110.37(c)
 21 CFR 117.20(b)(4), 117.37(b)(4), 117.37(c)

WALLS AND CEILINGS

Key Points: smooth, washable, impervious, good repair

Walls and ceilings of rooms in which food or food products are handled, processed, packaged or stored; or in which food containers, utensils and/or equipment are washed shall be of a durable, smooth, non-absorbent, washable, light-colored surface and be in good repair.

Regulations on this area can be found in:
Code of Maryland Regulations (COMAR) 10.15.04.09
 21 CFR 110.20(b), 110.20(b)(4)
 21 CFR 117.20(b), 117.20(b)(4)

DOORS AND WINDOWS

Key Points: outer openings effectively protected against entry of flies and rodents, outer doors self-closing; screen doors open outward

Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows, which shall be closed during dusty weather. All

openings to the outer air shall be effectively protected by any method to the extent to prevent the entry of insects, rodents and other pests (e.g. screening, air curtains, self-closing doors, etc.).

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.20(b), 110.20(b)(7)

21 CFR 117.20(b), 117.20(b)(7)

LIGHTING AND VENTILATION

Key Points: adequate lighting/ventilation all rooms, well ventilated to preclude odors and condensation, filtered air with pressure systems

All rooms in which food or food products are handled, processed, packaged or stored; or in which food containers, utensils and/or equipment are washed shall be well lighted and well ventilated. Ample light (natural or artificial) promotes cleanliness. Proper ventilation reduces odors, vapors and prevents condensation upon interior surfaces.

Safety type light bulbs, fixtures, skylights or other glass suspended over exposed food in any step of preparation shall be provided or any other means to protect against food contamination from glass breakage (ex. use of plastic shields, plastic sleeves with end caps, shatterproof bulbs, etc.). Fans and other air blowing equipment must be located in a manner that minimizes potential for contaminating food, food products, food contact surfaces and food packaging.

If not refrigerated rooms are mechanically ventilated so that excessive grease, vapors, steam, heat and odors are removed, filter air is provided to supply positive air pressure, and condensation and grease do not accumulate on room surfaces and equipment.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.20(b)(5)-(6)

21 CFR 117.20(b)(5)-(6)

PROCESS FLOW REQUIRED IN PLANT DESIGN

Key Points: plant built to prevent cross-contamination, separate rooms when required, adequate size for intended use, no direct opening into living quarters

An analysis of the physical flow of raw materials, food processing steps and finished products in the plant is highly recommended. Cross contamination and allergen contamination of products are food safety threats that can be avoided with a well-designed facility and operations. Designers should consult with owners and plan checkers prior to officially submitting of plans. Hopefully, this can reduce the time required for review and approval of submitted plans.

There *shall* be separate rooms for the cleaning of equipment/utensils, multi-use food containers, bottles and other equipment.

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There *may* be separate rooms required for some ready to eat food (RTE) products based on risk.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.20(b), 110.20(b)(1)-(2)

21 CFR 117.20(b), 117.20(b)(1)-(2)

TOILET-SEWAGE DISPOSAL FACILITIES

Key Points: no direct openings into process rooms, self-closing doors, clean, ventilated, adequate lighting, properly equipped, sewage/other wastes disposed of in sanitary manner

Every food plant shall be provided with toilet facilities conforming to the regulations of the appropriate regulatory agency.

Toilet rooms shall not open directly into any room in which food or food products are processed except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated (>2CFM) and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner so as not to contaminate food containers, utensils or equipment, or to create a nuisance or a public health hazard.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.37(b), (c), (d)

21 CFR 110.37(b), (c), (d)

WATER SUPPLY & SAFETY

Key Points: constructed properly, no direct/indirect connections between potable/non potable water, complies with appropriate bacteriological standards

Water for food plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality. Running water at a suitable temperature, under pressure as needed, shall be provided in all areas where required.

Private water sources shall comply with the specification outlined in the U.S. Environmental Protection Agency (EPA) ground water manual and the Bacteriological Standards outlined herein.

Plumbing shall be of adequate size and design, and adequately installed and maintained.

No cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.37(a), 110.37(b) (1)-(5), 110.80(a)(1), 110.80(b)(16)

21 CFR 117.37(a), 117.37(b) (1)-(5), 117.80(b)(1), 117.80(c)(16)

HANDWASHING FACILITIES

Key Points: located, properly equipped, clean, good repair, only hand sinks used for hand washing

Convenient hand washing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Hand washing facilities shall be kept in a clean condition and in good repair. Hand washing facilities shall be convenient to all toilets and to all rooms in which food plant operations are conducted.

Use of understandable signs directing employees to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty and when their hands may have become soiled or contaminated.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.37, 110.37(e) (1)-(6), 110.10 (b)(3)

21 CFR 117.37, 117.37(e), 117.10 (b)(3)

PLANT CLEANLINESS

Key Points: no unnecessary equipment, neat, clean, trash properly handled, no evidence of insects/pests

All rooms in which food and food products are handled, processed or stored, or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging and bulk food or packaged food product storage rooms.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.12

21 CFR 110.40(a)-(d), 110.35(c)-(d), 110.80(b)(6), 110.37(f), 110.20(b)(6)

21 CFR 117.40(a)-(d), 117.35(c)-(d), 117.80(c)(6), 117.37(f), 117.20(b)(6)

CONDITION & CLEANLINESS OF FOOD-CONTACT SURFACES

Key Points: good repair, smooth, non-toxic, approved single service articles and no reuse, effectively cleaned/ sanitized prior to using, proper strength of sanitizer, cleaning done in such a manner that it does not become a source of contamination, outer garments and gloves kept in a sanitary condition

All multi-use containers and equipment that food and food products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All food contact surfaces including outer garments and

gloves shall be maintained and kept clean and in sanitary condition. Articles intended for single-service use shall not be reused.

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling and storage of food or food products shall be effectively cleaned and sanitized before each use.

Equipment must be provided to properly clean and sanitize food contact surfaces. This may be accomplished by a three-compartment sink for washing, rinsing and sanitizing food contact surfaces of equipment. For large pieces of equipment, a clean in place method may be utilized with adequate drainage provided accordingly.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.10(b)(1) & (5), 110.35(d)(1), (2) & (4), 110.40(a)-(b), 110.80(b)(1), 110.80(b)(10), 110.80(b)(13)(ii)

21 CFR 117.10(b)(1) & (5), 117.35(d)(1)-(3), 117.40(a)(1)-(6) & (b), 117.80(c)(1), 117.80(c)(10)

STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

Key Points: stored to assure drainage, protected from contamination

After cleaning, all multi-use food or food product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

Containers shall be stored inverted, if practicable, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials or otherwise protected from contamination.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.10

21 CFR 110.35(e)

21 CFR 117.35(f)

STORAGE OF SINGLE- SERVICE CONTAINERS, UTENSILS

Key Points: received, stored, handled in sanitary manner, single service articles not reused

Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags and other single-service articles (plastic forks, single service ladles, etc.) for use in contact with food and food products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.09

21 CFR 110.35(d)(4)

21 CFR 117.35(d)(3)

PROPER LABELING, STORAGE & USE OF TOXIC COMPOUNDS

Key Points: only approved pesticides used, properly identified, properly stored

Chemicals, poisonous and toxic materials shall be identified, held and stored in a manner to preclude the contamination of food and food products, or ingredients of such food and food products, or the product contact surfaces of all containers, utensils and equipment.

Use of pesticides is permitted only under precautions and restrictions that will protect against contamination of food, food-contact surfaces or food-packaging materials.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.12

21 CFR 110.35(b)(2), 110.35(c)

21 CFR 117.35(b)(2), 117.35(c)

PROTECTION FROM CONTAMINATION (ADULTERATION)

Key Points: operations conducted/located to preclude food/food product/food product contact surface contamination, air and steam used to process foods in compliance, protecting food in outdoor fermentation vessels.

Equipment and utensils used in the food plant shall be of adequate design and material as to be easily cleaned and properly maintained to preclude the adulteration of food. Cleaning and sanitizing of equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces or food-packaging materials.

The codes do not dictate the exact type of equipment that is needed by a food processor. Whatever the equipment, it must be designed, constructed and used in a manner that does not allow for the contamination or adulteration of the food.

All operations in the food plant including but not limited to receiving, transporting, preparing, manufacturing, packaging and storing shall be conducted in accordance with adequate sanitation principles.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.10

21 CFR 110.20(b)(4), 110.35(a), 110.40(a), 110.80, 110.80(a)(5), 110.80(a)(7), 110.80(b)(5), 110.80(b)(7), 110.80(b)(10), 110.80(b)(12), 110.80(b)(13), 110.93.

21 CFR 117.20(b)(4), 117.35(a), 117.40(a)(1)-(6), 117.80(a)(1)-(6), 117.80(b)(5), 117.80(b)(7), 117.80(c)(5), 117.80(c)(7), 117.80(c)(10), 117.80(c)(12), 117.80(c)(13), 117.93.

PERSONNEL – CLEANLINESS

Key Points: hands washed often as necessary, rewashed as needed, clean outer garments, effective hair restraints, no use of tobacco/gum, remove jewelry, clothing storage

Hands shall be thoroughly washed before commencing food plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, pasteurization, storage, transportation or packaging of food and food product, containers, utensils and equipment, shall wear clean outer garments. All persons, while engaged in the processing of food and food products, shall wear adequate hair coverings and shall not use tobacco.

Any person who by medical examination, or supervisory observation is shown to have or appears to have an open lesion, cuts, boils, sores, open wounds and like items; illness, or other source of microbial contamination whereby there is a reasonable chance to contaminate food, food products, food product contact surfaces, or food packaging shall be excluded. Personnel are to be trained/instructed to report such things to supervision.

Personnel responsible for identifying sanitation failures or food contamination have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean safe food.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.11

21 CFR 110.10(b)(1) - (9), 110.10(c)

21 CFR 117.10(b)(1)-(9), 117.4(c).

TRANSPORTATION, WAREHOUSE & DISTRIBUTION

Key Points: adequate storage, capable of protecting food/food products in transit and during storage, capable of maintaining food temperature as appropriate, clean, no toxics transported

Adequate and suitable floor space shall be provided for the storage of foods, ingredients and/or finished products. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical and microbial (including radiological) contamination as well as against deterioration of the food and the container.

All vehicles used for the transportation of food or food products shall be constructed and operated so that the food or food product is maintained at the appropriate temperature and to protect the food from contamination. Vehicles may not be used to transport or contain any substances that may be toxic or harmful to humans.

Regulations on this area can be found in:

Code of Maryland Regulations (COMAR) 10.15.04.13

21 CFR 110.93

21 CFR 117.93

SURROUNDINGS/PLANTS-GROUNDS

Key Points: neat, clean, no harborages, no pooled water, approved pesticides used properly, rooftops clean

Food plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance. Waste material shall be stored in suitable covered containers.

No accumulation of trash, garbage or similar waste in areas adjacent to the food plant. This includes properly storing equipment, removing waste and trash, cutting weed/grass/other vegetation in the immediate vicinity of the plant buildings and structures that may constitute harborage areas for pests.

Only insecticides and rodenticides approved for use by the regulatory agency and/or registered with EPA shall be used for insect and rodent control.

Areas that may contribute to food contamination through seepage, foot borne filth, etc., shall be drained adequately. Said drainage shall serve to preclude a harborage/ breeding area for pests.